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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,254	12/27/2000	Siamak Tabibzadeh	0152.00384	8450

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,254	TABIBZADEH, SIAMAK	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41,46-48,54,61-63,66,67,69,70,76-79 and 86-95* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *70* is/are allowed.

6)☒ Claim(s) *41,46-48,54,61-63,66,67,69,76-78 and 86-95* is/are rejected.

7)☒ Claim(s) *79* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 41, 46-48, 54, 61-63,66-67,69-70,76-79 and new claims 86-95 are pending.

2. ***Specification The*** disclosure objected to because of the informalities has been obviated through amendment of the first sentence of the Specification.

3. ***Double Patenting Withdrawn :C***laim 71, 79 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,683,156 has been obviated through cancellation of claim 71 and amendment of claim 79 to no longer encompass the full protein.

4. ***Double Patenting Withdrawn*** Claim 80 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,294,662. has been obviated through cancellation of claim 80.

5. ***Rejection Withdrawn, Claim Rejections - 35 USC § 102*** The rejection of claims 41,45-46,54-56,59, 61-63, 64,66,68,71 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Feinberg et al (US Pat. 5,395,825) in light of the cancellation of claims and amendment of claims to recite the term "consisting of".

6. ***Rejection Withdrawn, Claim Rejections - 35 USC § 102*** The rejection of claims 64, 66, 68, 69 and 71 under 35 U.S.C. 102(b) as being anticipated by Wieczorek et al (July 1995 (chicken TGF-Beta 4) is herein with drawn in light of the amendment of the claims to no longer read on TGF-beta 4 protein alone or antibodies directed to any portion of TGF-Beta 4.

Allowable Subject Matter

7. Claim 70 defines over the prior art of record and is allowed.

Rejections Maintained/Response to Arguments

8. Applicant's arguments filed April 24, 2006 have been fully considered but they are not persuasive.

9. ***Double Patenting Maintained*** The rejection of claims 41, 54 ,61 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 3 and 8 of U.S. Patent No. 5,916,751 is traversed on the grounds that the claim limitations of claim 42 have been incorporated into the independent claims that were not included in the prior rejection, and therefore it is obviated.

10. It is the position of the examiner that upon reconsideration of the definitions provided by the Specifications, one of the preferred embodiments is utilization of mRNA in the instantly claimed methods and the allowed method of US Pat. 5,916,751. The rejection is maintained in light of an effective terminal disclaimer has Not been submitted.

7. **Rejection Maintained**: The rejection of claims 41, 46-48 and 54, 61-63, 78 and new claims 86-95 (written description)under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention is traversed on the grounds that "Applicant respectfully asserts that the subject specification does provide adequate written description for various species of ebaf protein and polynucleotides encoding the same, and states that the "Examiner asserts that the subject specification does not provide adequate written support for species of ebaf protein other than a human ebaf protein and polynucleotides encoding the human ebaf protein."

11. It is the position of the examiner that the written description rejection was based upon the fact that the claims are directed to any human endometrial bleeding associated factor protein encoded by any nucleic acid, the nucleic acid being RNA (newly amended claims), but the instant Specification only describes SEQ ID NO 1 (nucleic acid sequence) that encodes a EBAF protein, and not a genus of nucleic acids that encodes any human protein allelic variant, or homolog thereof with the same or equivalent function, which can be referred to as a human endometrial bleeding associated factor. The examiner did not state that applicant had described a genus of human genes that included both intron and exon nucleotide sequences, but only SEQ

ID NO 1 which encodes EBAF protein. Bassi et al (1998) teaches that there are three exon regions for Lefty-A, another name for EBAF, the gene for humans which is located on chromosome 1q42; the instant Specification does not describe the three exons and the chromosomal location for the human ebaf gene. The specification does not provide adequate written description to support for a genus of species homologs to SEQ ID NO: 1. There is inadequate written description to support claims to kits, compositions, and methods of use of any ebaf nucleic acid or a protein that encodes a protein to which antibodies are made, wherein the nucleic acid is only defined as evidence the functional characteristics of an ebaf molecule.

More than a statement of biological function is required to satisfy the 35 USC 112 first paragraph, written description requirement for a genus of DNA molecules. See e.g. Amgen lnc. v. Chuzai Pharmaceutical Co. Ltd., 18 U.S.P.Q.Zd 1016, 1027 (CAFC 1991); and Fiers v. Revel, 25 U.S.P.Q.Zd 1601, 1604-05 (CAFC 1993). ln Amgen v. Chuzai, the Court of Appeals for the Federal Circuit stated that "it is not sufficient to define (a DNA) solely by its principal biological property, e.g. encoding of human erythropoietin." Id. at 1021. Rather, what is necessary is that (the applicant) provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims." Id. at 1027. ln these statements, the court has expressly stated that a DNA molecule must be described by means of description other than by naming the encoded protein to satisfy the 35 USC 112 first paragraph written description requirement. More recently, the Federal Circuit again took this position. In the case University of California v. Eli Lillv and Co., 43 U.S.P.Q.Zd 1398, at 1406 (1997), the court stated that defining a CDNA by its function 'tis only a definition of a useful result rather than a definition of what achieves that result." The court also stated that such a description does not define any

structural features commonly possessed by members of the genus (of claimed CDNAS) that distinguish them from others." ld. Thus, it is clear that identification of a polynucleotide by naming the polypeptide it encodes is not sufficient. In the present case, the only description that the applicant has provided is SEQ ID NO: 1 that encodes an edaf protein and this requirement is derived from the specification rather than being explicit in the claims. The disclosed single species does not provide descriptive support for a highly variable genus; there is clearly insufficient to support the claimed genus of ebaf nucleic acids that encode a genus of ebaf proteins, that are used to generate a genus of ebaf antibodies. The rejection is maintained for reasons of record.

12. ***Rejection Maintained***: The rejection of claims 66, and 69 under 35 U.S.C. 102(a) as being anticipated by Meno et al (Nature, May 9, 1996) is traversed on the grounds that the claims have been amended to recite the phrase "consists of" thus obviating the applied reference.

13. It is the position of the examiner that the isolated antibodies/antisera of Meno et al were produced to a peptide that shared 100% sequence identity over the amino acid sequences ASDGAL and PRRLQ of the instant SEQ ID NO 3 (see Figure 2, oligopeptide), and antibodies directed against these amino acids would also specifically bind to SEQ ID NO 3. Meno et al still disclose the instantly claimed invention as now claimed. The antibodies of Meno et al still anticipate the instantly claimed invention.

14. ***Rejections Maintained Claim Rejections - 35 USC § 103*** The rejection of claims 67 under 35 U.S.C. 103(a) as being unpatentable over Meno et al (May 1996) and the rejection of

claims 76-78 under 35 U.S.C. 103(a) as being unpatentable over Meno et al further in view of Foster et al (US Pat. 4,444,879) are traversed together on the grounds that: the claims have been amended to recite the term "consists of", thus obviating the applied reference.

15. It is the position of the examiner that the immunogen of Meno et al was a peptide that shared 100% sequence identity over the amino acid sequences ASDGAL and PRRLQ of the instant SEQ ID NO 3 (see Figure 2, oligopeptide), and antibodies directed against these amino acids would also specifically bind to SEQ ID NO 3. The antibodies directed to EBAF would consist of antibodies that would be immunoreactive to SEQ ID NO 3. The rejection is maintained for reasons of record and responses set forth herein. See In re Erlich 1988.

New Claim Limitations/New Grounds of Rejection/Objection

Claim Objections

16. Claim 79 is objected to because of the following informalities: Claim 79 has been amended to recite the phrase "A kit comprising in one or more containers: a peptide consisting of the amino acid sequence shown in SEQ ID NO .3." The sentence recites a ":" colon in the middle of the sentence; this should be removed . Amendment of the claim to recite ---A kit comprising the peptide of claim 70 in one or more containers---- could obviate this objection. Appropriate correction is required.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
June 26, 2006

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